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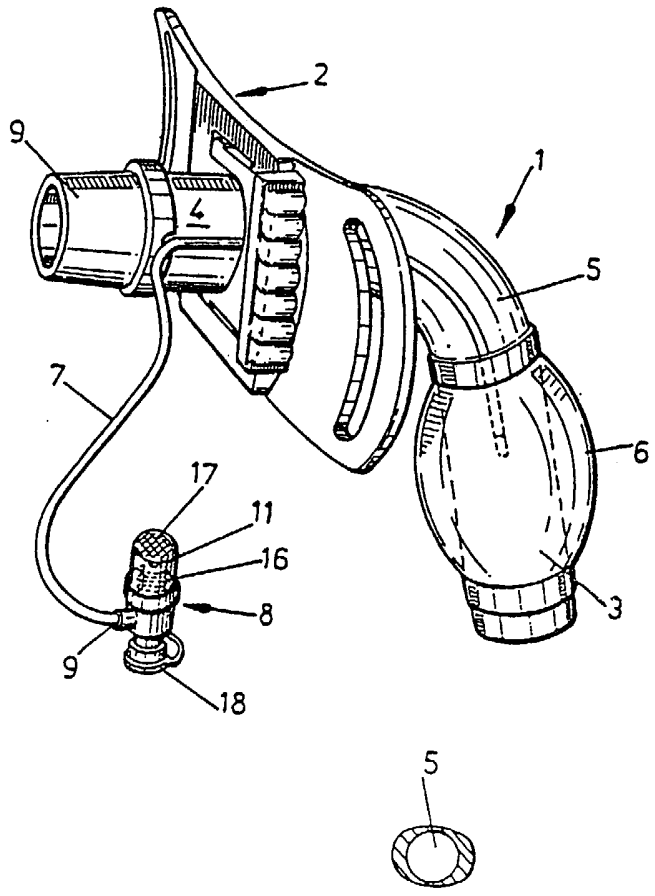
(57) Abstract

Several developments for tubular intubation devices are disclosed. In one development, the intubation device has over at least a portion of its length two opposed wall sections which are of lesser thickness than the wall sections by which they are connected. As a result, the device has a greater degree of transverse flexibility about the reduced wall thickness sections than about the wall sections of greater thickness. Intubation devices may be provided with balloons which are of an elastomeric polyurethane. Pressure within a balloon on the intubation device may be monitored by a pressure indicator device having a bellows working within a transparent housing. The position of the bellows provides an indication of the pressure. An arangement for supporting a tracheostomy tube on the neck of a patient is also disclosed.



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INTUBATION DEVICES

The present invention relates to intubation devices which are used to assist breathing in human or animal patients. The invention relates particularly, but not exclusively, to intubation devices in the form of endotracheal tubes and tracheostomy tubes.

Endotracheal tubes are used principally for cases where short-term assistance of breathing is required, e.g. whilst a patient is under anaesthetic during a surgical operation. The endotracheal tube is introduced into the mouth or nose of the patient and advanced so that its inner end locates within the trachea of the patient. The outer end of the tube is external of the patient's mouth and is generally connected to a ventilator apparatus whereby air is introduced through the endotracheal tube into the patient's lung.

Tracheostomy tubes are used for longer term intubation and are introduced into the trachea through a stoma in the neck of the patient. Once again the outer end of the tracheostomy tube may be connected to a ventilator for supplying air into the patient's lungs.

A first aspect of the present invention relates to constructions of intubation devices which facilitate location of the device in the airway of a patient.

According to a first aspect of the present invention there is provided a tubular intubation device having over at least a portion of its length two opposed wall sections which are of lesser thickness than the wall sections by which they are connected whereby the device has a greater degree of transverse flexibility about said reduced wall thickness sections than about the wall sections of greater thickness.

Typically the "lesser" wall thicknesses will be in the range 0.5-1.5mm whereas the "connecting" wall thicknesses will be greater and typically be in the range 1-3mm. Typically the ratio of the "lesser" : "connecting" wall thicknesses will be about 1:2.

The provision of the reduced wall thickness ensures that the intubation device has an enhanced degree of flexibility for bending in one plane (the "first" plane) transverse to its length as compared to the plane perpendicular thereto. Thus insertion of the device into a patient is facilitated. Moreover, movements of the patient are accommodated by the flexing in the first plane so that the device readily conforms to the position of the patient without being forced

against the trachea which could cause pressure and erosion. Nevertheless the provisions of the thicker wall sections ensures that the device will not "collapse" if subjected to a relatively large degree of flexing if bent too severely in the first plane. This is of course particularly important because collapse of the tube would prevent passage of the ventilating air along the intubation device.

The first aspect of the invention may be applied to endotracheal tubes and tracheostomy tubes.

In the case of an endotracheal tube the reduced wall thickness may be provided along a significant portion of the length of the tube to facilitate insertion of the device via the mouth or nose of a patient into the trachea.

A tracheostomy tube embodying the first aspect of the invention may comprise a first section for location in the trachea of a patient and a second section into which ventilating air is supplied, the two sections being angled relative to each other and being connected by a bend region whereof the wall thicknesses on the inside and on the outside of the bend are less than the wall thicknesses at the side of the bend so as to give the enhanced flexibility in the plane of the bend.

Generally, the section of the intubation device which locates within the trachea of the patient will be provided with an inflatable balloon for use in providing a seal against the inside of the trachea.

A second aspect of the invention relates to intubation devices whereof that portion of the device which locates within the trachea of the patient is provided with an inflatable balloon to provide a seal against the trachea. Prior art intubation devices have utilised balloons which are inflated to a relatively high pressure and which therefore provide a relatively "hard" balloon. Such balloons (which may for example be rubber or high pressure PVC) are relatively non-deformable in the inflated condition. This is a disadvantage because of the structure of the trachea. More particularly, the back of the trachea is of a soft material whereas the remainder comprises "rings" of cartilage. Additionally the inner surface of the trachea is covered by a delicate mucous membrane. The balloon does not readily deform to conform to the inner surface of the trachea. In fact, the opposite is to a certain extent true in that the trachea is partially forced to

conform to the balloon. However this gives rise to pressure points within the trachea, which are disadvantageous and which may be uncomfortable for the patient, and an imperfect seal may be obtained.

The prior art has also employed so-called high volume, low pressure balloons which may for example be formed of PVC. Since PVC is not elastomeric, it does not fold properly when collapsed and therefore does not lie closely against the tubular body of the intubation device. Additionally some of the folds may be retained when the balloon is inflated so that an imperfect seal is obtained. This has the disadvantage that acids from the stomach which pass up the oesophagus may be able to travel down the trachea past the balloon. A further problem is that, because PVC is not an elastomeric material, over inflation may cause the balloon to become hard with the attendant disadvantages discussed above.

It is an object of the second aspect of the present invention to obviate or mitigate these disadvantages.

According to a second aspect of the present invention there is provided a tubular intubation device comprising a first section for location in the trachea of a patient connected to a second section into which ventilating air is supplied, an inflatable balloon provided around said first section for providing a seal against the trachea, and an inflation line along which fluid pressure may be supplied to the balloon wherein said balloon is of an elastomeric polyurethane.

The use of an elastomeric polyurethane provides a balloon which is capable of forming a soft seal against the inner surface of the trachea by conforming to the shape thereof. Additionally, the balloon still provides a soft seal even if over inflated.

A third aspect of the present invention also relates to intubation devices provided with balloons which are inflated for providing a seal against the trachea. Care must obviously be taken to ensure that the balloons are inflated to the correct pressure. Under inflation implies that the seal may not be properly formed whereas over inflation can give rise to pressure points within the trachea. Prior art intubation devices have included a so-called "pilot balloon" which is provided externally of the patient's body in communication with the inflation line. The pressure in the pilot balloon corresponds to that in the balloon forming the seal against

the trachea. A measure of the pressure in the latter balloon has been gauged simply by squeezing the pilot balloon. However this method is somewhat subjective and may lead to an incorrect assessment of whether or not the main balloon is correctly inflated. An alternative proposal has been to use a pressure gauge which is attached to the inflation line to provide a measure of the pressure within the main balloon. Such pressure gauges are generally relatively expensive, delicate, and not always available when required.

It is therefore an object of the third aspect of the invention to obviate or mitigate these disadvantages.

According to the third aspect of the present invention there is provided a tubular intubation device comprising a first section for location in the trachea of a patient connected to a second section into which ventilating air may be supplied, an inflatable balloon provided around said first section for providing (when inflated) a seal against the trachea, and an inflation line in communication with the interior of the balloon and along which fluid pressure may be supplied to effect expansion of the balloon to form said seal wherein said inflation line is associated with a pressure indicator device adapted to communicate with the inflation line and a source of said fluid pressure, said indicator device having a pressure indicator element which is provided, and visible, within a housing to provide a visible indication of the pressure in the balloon.

Since the pressure indicator element is capable of communicating with the source of fluid pressure and also with the interior of the main balloon, the element does not need to be connected to the inflation line each time a pressure assessment is to be made. Furthermore, the element provides a visible representation of the pressure within the balloon and therefore a more accurate estimate than that which is obtained by squeezing a pilot balloon.

Preferably the indicator element is of a bellows-type structure, the interior of which communicates with the fluid supply line. Preferably also the bellow-like pressure indicator element is movable within a housing which is transparent to provide the visual pressure indication. The housing may, for example, have a graduated scale indicative of pressure. More simply, the housing may have a line positioned such that movement of the indicator element beyond the

line indicates over inflation of the balloon. Alternatively, the housing may have a coloured area (e.g. red) positioned such that movement of the indicator element into the coloured area indicates over inflation.

According to a fourth aspect of the present invention there is provided a pressure indicator device for use in indicating the inflation condition of a balloon provided on a tubular intubation device, the pressure indicator device comprising a bellows arrangement which is extensible and contractible within a housing, means for connecting the pressure indicator device to an inflation line for effecting inflation of the balloon, and means for connecting the device to a source of fluid pressure.

Preferably the pressure indicator device incorporates a one-way valve arrangement through which the fluid pressure is supplied.

A fifth aspect of the present invention relates to the location of intubation devices (particularly tracheostomy tubes) in position on a patient.

According to a fifth aspect of the present invention there is provided a tubular intubation assembly comprising a tubular intubation device having a first section for location in the trachea of a patient connected to a second section into which ventilating air is supplied, and location means for locating the intubation device on a patient, said means comprising a support member which is intended for location on the body of the patient and through which said second section extends, and securement means for locating said second section in position within the support member.

Preferably the support member comprises a slideway, and the positioning member is a slide member adapted to locate in the slideway and clamp the second section within the support member. The slide member may have jaws which engage around the outer surface of the second section of the tracheostomy tube. The inner surfaces of the jaws may be provided with teeth or like formations which engage the outer surface of the second section and serve to clamp the tube in position. Preferably the outer surface of the second section is of a relatively soft material compared to a relatively more rigid interior. The soft surface facilitates clamping of the jaws on the outer surface of the tube whilst the more rigid interior prevents any collapse due to the clamping action.

According to a sixth aspect of the present invention there is provided location means for locating a tubular intubation device in position on a patient, the location means comprising a support member which is intended for location on the body of the patient and through which said second section extends, and securement means for locating said second section in position within the support member.

It will be appreciated that the fifth and sixth aspects of the invention relate particularly to tracheostomy tubes whereas the remaining aspects of the invention may be applied either to endotracheal or tracheostomy tubes. It will also be appreciated that any one aspect of the present invention may be used singly or in combination with one or more further aspects of the invention.

Additionally, intubation devices in accordance with any aspect of the invention may be provided with silver ions on either the inner or outer thereof. The silver ions act as a bacteriostat.

The invention will be further described by way of example only with reference to the accompanying drawings, in which:

Fig. 1 is a perspective view of one embodiment of tracheostomy tube assembly incorporating various aspects of the invention;

Fig. 2 is a schematic cross-sectional view of the tracheostomy tube illustrated in Fig. 1, but omitting details of the inflation balloon, inflation line, and pressure indicator;

Figs. 2a and 2b are respectively cross-section on the lines a-a and b-b in Fig. 2;

Fig. 2c is similar to Fig. 2a but shows a "collapsed" condition of the tube section;

Fig. 3 is a detail of the pressure indicator assembly illustrated in Fig. 1;

Fig. 4 shows a detail of the rigid insert provided at the end of the tracheostomy tube;

Fig. 5 is a view of the tracheostomy tube location device looking generally in the direction of arrow A in Fig. 1 and showing also part of the tracheostomy tube; and

Fig. 6 is a sectional view on the line V-V of Fig. 5.

Referring to Fig. 1, the illustrated tracheostomy tube assembly comprises a tracheostomy tube 1 and a location arrangement 2. The tube 1 comprises a first section 3 (intended for location in the trachea

of a patient) connected to a second section 4 (for connection to a ventilator) through a bend region 5. Provided around the second section 3 is a balloon 6 which is shown in an inflated condition. In accordance with the second aspect of the invention the balloon is of a soft polyurethane. Inflation of the balloon is effected by means of an inflation line 7 which may for example be provided along a groove formed in the outer surface of the tracheostomy tube 1. The inflation line 7 is connected to a pressure indicator device 8 (in accordance with the third and fourth aspects of the invention) for monitoring the pressure within balloon 6. The pressure indicator device 8 may also be connected to a source of fluid pressure (not shown) for effecting inflation of the balloon.

Referring now to Fig. 2, it will be seen that the end of the second section 4 is provided with an end connector 9 which is rooted within the walls of the end section 4. Apart from the connector 9, the tube 1 is of a relatively soft polyurethane. Connector 9 is of a relatively rigid polyurethane. The reason for this arrangement will be described below.

As shown in Fig. 2a, the cross-section at the bend region 5 is (in accordance with the first aspect of the invention) such that the walls at the inside and outside of the bend are of lesser thickness than at the sides of the bend. This is in contrast to the cross-section of the first section 6 of the tube 1 in which the walls are of generally uniform thickness (see Fig. 2b).

The advantage of the differential wall thickness around the bend 5 is that, with the lower thickness around the inside and outside of the bend the tube 1 has an improved degree of flexibility for angular movement of the two sections 3 and 4 towards and away from each other to assist positioning of the tube in a patient. If however the tube should become excessively bent at the region, then as illustrated in Fig. 2c the tube will not collapse completely but is maintained partially opened by virtue of the extra wall thickness at the side of the bend.

Referring now to Fig. 3, it will be seen that the pressure indicator device 8 (illustrated on a much enlarged scale) has a body provided with fluid transfer ports 9 and 10, the former being connected to the inflation line 7 and the latter to a source (not

shown) of fluid pressure. The body of the indicator device is provided with a generally transparent bell-like housing 11. Furthermore an insert 12 is clamped in position as shown by the housing 11 and is further located in position by an upper circular plate 13a of a one-way valve 13. The body of valve 13 is generally cruciform and the lower end is provided with a recess 13b as shown.

The insert 12 comprises an axially compressible cylindrical section 14 with apertures 15 which permit communication between ports 9 and 10, and a bellows arrangement 16 the interior of which communicates with line 7 (via apertures 15). The bellows arrangement is capable of "working" within the housing 11, and the level at which the top 16a of the bellows is positioned within the housing is an indication of the pressure in line 7 (and thus in balloon 6).

A coil spring 14a is provided around the body 14 as shown between a lower flange 16b of the bellow and a flange 14b of the body.

Provided at the top of the otherwise transparent housing 11 is a coloured area 17 (e.g. red) positioned such that a rise of the bellows top 16a into the area 17 indicates over inflation of the balloon 6. obviously the housing may be provided with additional markings which are indicative of a satisfactory degree of balloon inflation.

To inflate the balloon 6, the outlet end of a syringe (not shown) is located in the recess 13b and the syringe is advanced so that the one-way valve causes the flanges 14b and 16b to move relatively towards each other against the force of spring 14a. This is allowed by virtue of the compressibility of cylindrical section 14. When fully inserted, the syringe seals against the lower end of the port 10. Fluid (e.g. air) from the syringe may now be injected and enters the annular space around body 14 before passing radially inwardly through apertures 15 into the inflation line 7. When the balloon has been satisfactorily inflated, the syringe may be withdrawn and the valve 13 closes.

It will therefore be appreciated that the indicator device 8 provides an immediate, accurate representation of the pressure within the balloon during inflation thereof. After inflation of the balloon has been completed, the port 10 may be disconnected from the source of fluid pressure and covered by a fluid tight cap 18 (see Fig. 1).

Reference is now made to Figs. 2 and 4. As indicated previously

the second section 4 of the tube 1 is provided with an end connector 9 which as illustrated in Fig. 4 incorporates a head 19 and a cylindrical extension 20 with apertures 21. The tracheostomy tube is formed by a moulding operation during which the walls of the tube section 4 are moulded around the cylindrical extension 20. During moulding, the plastics material of the tube 2 passes through the apertures 21 whereby the extension provides a root for the connector 9 within the tube section 4.

The provision of the cylindrical extension 20 in the tube wall, the differential wall thicknesses at the bend 5, and the uniform wall thickness in the first section 3 means that the tube has different stiffnesses in each of the three sections 3, 4 and 5. In section 4, the device is rigid at the stoma to prevent the tube collapsing by contraction of the tissue. At the section 5, the device is more flexible to permit insertion whereas section 3 may be relatively soft and flexible in all directions to avoid forces acting on the trachea.

Reference was made above to the location assembly 2 (which is in accordance with the fifth and sixth aspects of the invention). This is illustrated schematically in Fig. 2 and in more detail in Figs. 5 and 6. The assembly 2 comprises a plate-like support member 22 and a sliding clamp element 23. The support member 22 has a centrally located aperture 24 and is formed so that its rear surface is curved in two mutually perpendicular directions which permits the support member to be positioned on the front of the neck. Thus the rear surface of the support member is curved as shown in Fig. 1 to permit location around the curvature of the patient's neck, and is further curved as viewed in Fig. 6 to permit conformity with the angle of the patients chin.

Also, as shown in Fig. 6, the support 22 has two apertures 25 for use in location of the support member on the neck of a patient.

The clamp 23 has two spaced arms 26 providing jaws between which the second section 4 of the tube is clamped, as described in more detail below. The arms have a cross-section as illustrated in Fig. 6 which will be seen to include flanges 26a provided along the outer edges of the arms. At one end, the arms are bridged by a connecting piece 27 whereof the edge 27a included by the arms is generally semi-circular with a radius corresponding to that of

aperture 24. On their opposed surfaces, the arms 26 are provided with teeth 28, and at their free ends the arms are provided with noses 29 as shown.

The clamp 23 is releasably located on the plate-like support 22 by a slideway arrangement 30 which comprises a pair of slideways 31 (which have a cross-section as illustrated in Fig. 6 so as slidably to receive the flanges 26a (of arms 26). The slideway arrangement further comprises a central portion 32 (bridging the slideways 31) having an arcuate edge 32a extending about half-way around the aperture 42 and further having edges 32b which opposed to the adjacent slideway 31 to form a section in which the free ends of the arms 26 (of clamp 23) may be received. A further feature of the slideway arrangement 30 is the provision of a projection 33 on the edge 32a. This projection is intended to locate in a recess 34 provided in (and extending along) the outer surface of the second section 4 of the tracheostomy tube.

The free ends of the slideways 31 have noses 35 past which the noses 29 of the arms 26 must ride during entry of the clamp into the slideway. It is in fact envisaged that the sliding clamp 23 will be located in position in the slideway during manufacture, i.e. prior to supply of the device.

Prior to location of the tracheostomy tube on a patient, the sliding clamp 22 is withdrawn as far as possible, i.e. until the noses 29 and 35 abut against each other. The support 22 is next positioned on the second section of the tube adjacent the connector 9 and such that projection 33 locates in recess 34.

The first portion 3 of the tracheostomy tube is now inserted through a stoma in the neck of the patient until said portion 3 locates in the trachea. If necessary, support 22 may now be moved along the second section towards the neck of the patient. When the support 22 is in the required position, clamp 23 is moved along the slideway arrangement. The teeth 28 now grip the relatively soft outer surface of the second section 4 of the tracheostomy tube whereby the support 22 is held firmly in position relative to the tube. It should at this stage be mentioned that the teeth 28 have relatively gently curved leading edges so that they pass easily over the relatively soft outer material of the section 4 but nevertheless have relatively sharp gripping edges to grip the section 4. Collapsing of the second section

is prevented by virtue of the part 20. Relative rotation between the tracheostomy tube and the support 22 is prevented by the location of projection 33 in recess 34.

A flexible strap (not shown) may then be passed around the back of the patient's neck and affixed to the support member 22 through the apertures 25 thereof.

CLAIMS

1. A tubular intubation device having over at least a portion of its length two opposed wall sections which are of lesser thickness than the wall sections by which they are connected whereby the device has a greater degree of transverse flexibility about said reduced wall thickness sections than about the wall sections of greater thickness.

2. A device as claimed in claim 1, wherein said opposed wall sections have a thickness of 0.5-1.5mm and the wall sections by which they are connected have a greater thickness in the range 1-3mm.

3. A device as claimed in claim 1 or 2, wherein the ratio of the thickness of the opposed wall sections to the wall sections by which they are connected is about 1:2.

4. A device as claimed in any one of claims 1 to 3 comprising a first section for location in the trachea of a patient and a second section into which ventilating air is supplied, said first and second sections being angled relative to each other and are connected by a bend region at which said opposed walls of reduced thickness are located.

5. A tubular intubation device comprising a first section for location in the trachea of a patient connected to a second section into which ventilating air is supplied, an inflatable balloon provided around said first section for providing a seal against the trachea, and an inflation line along which fluid pressure may be supplied to the balloon wherein said balloon is of an elastomeric polyurethane.

6. A tubular intubation device comprising a first section for location in the trachea of a patient connected to a second section into which ventilating air may be supplied, an inflatable balloon provided around said first section for providing (when inflated) a seal against the trachea, and an inflation line in communication with the interior of the balloon and along which fluid pressure may be supplied to effect expansion of the balloon to form said seal wherein said inflation line is associated with a pressure indicator device adapted to communicate with the inflation line and a source of said fluid pressure, said indicator device having a pressure indicator element which is provided, and visible, within a housing to provide a visible indication of the pressure in the balloon.

7. A device as claimed in claim 6, wherein the indicator element is

of a bellows-type structure, the interior of which communicates with the fluid supply line.

8. A device as claimed in claim 7, wherein the bellows-like pressure indicator element is moveable in a housing which is transparent to provide the visual pressure indication.

9. A device as claimed in any one of claims 6 to 8 provided with a one-way valve arrangement through which the fluid pressure is supplied.

10. A pressure indicator device for use in indicating the inflation condition of a balloon provided on a tubular intubation device, the pressure indicator device comprising a bellows arrangement which is extensible and contractible within a housing, means for connecting the pressure indicator device to an inflation line for effecting inflation of the balloon, and means for connecting the device to a source of fluid pressure.

11. A tubular intubation assembly comprising a tubular intubation device having a first section for location in the trachea of a patient connected to a second section into which ventilating air is supplied, and location means for locating the intubation device on a patient, said means comprising a support member which is intended for location on the body of the patient and through which said second section extends, and securement means for locating said second section in position within the support member.

12. An assembly as claimed in claim 11, wherein the support member comprises a slideway, and the positioning member is a slide member adapted to locate in the slideway and clamp the second section within the support member.

13. An assembly as claimed in claim 12, wherein the slide member has jaws which engage the outer surface of the second section of the tube.

14. An assembly as claimed in claim 13, wherein the inner surfaces of the jaws are provided with teeth or like formations.

15. An assembly as claimed in any one of claims 11 to 14, wherein the outer surface of the second section is of a relatively soft material as compared to a relatively more rigid interior.

16. Location means for locating a tubular intubation device in position on a patient, the location means comprising a support member which is intended for location on the body of the patient and through

which said second section extends, and securement means for locating said second section in position within the support member.

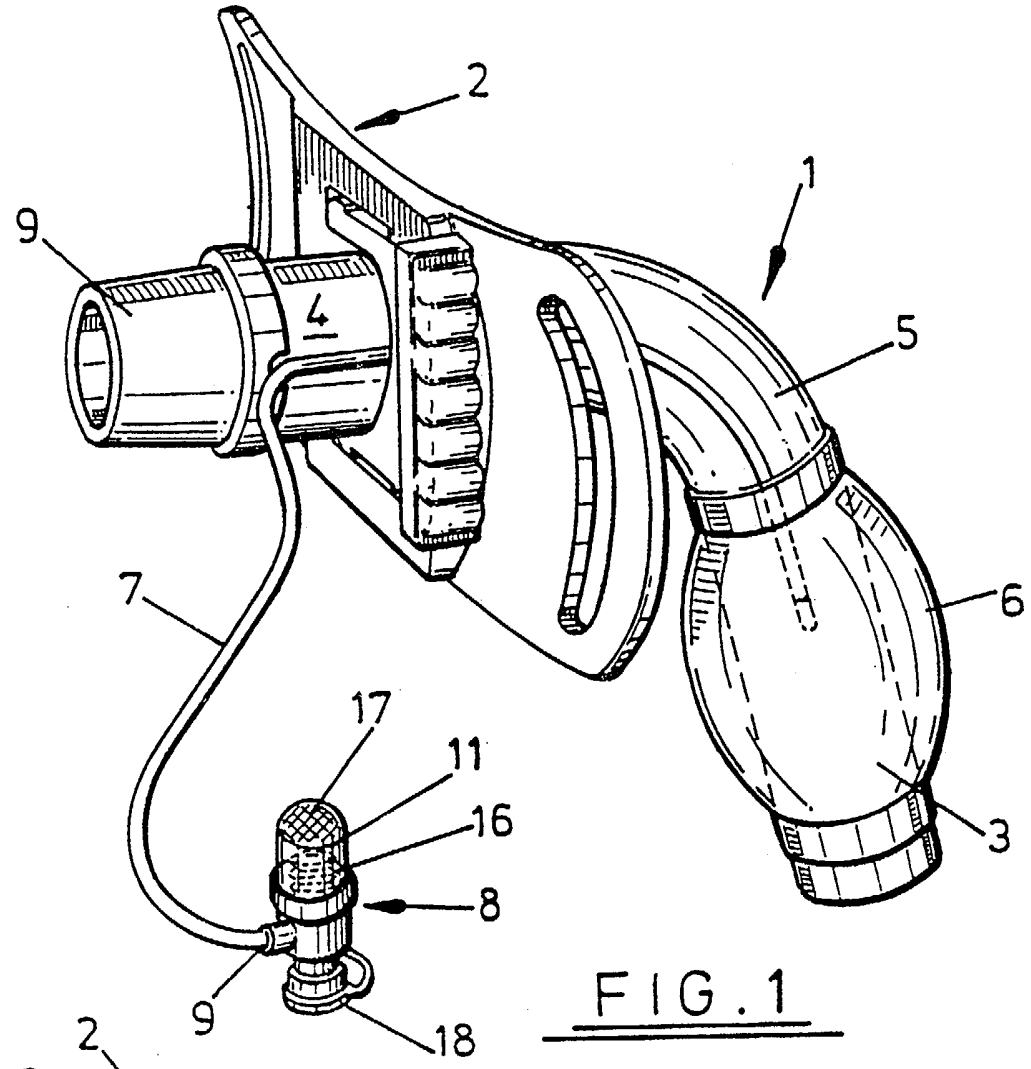

FIG. 1

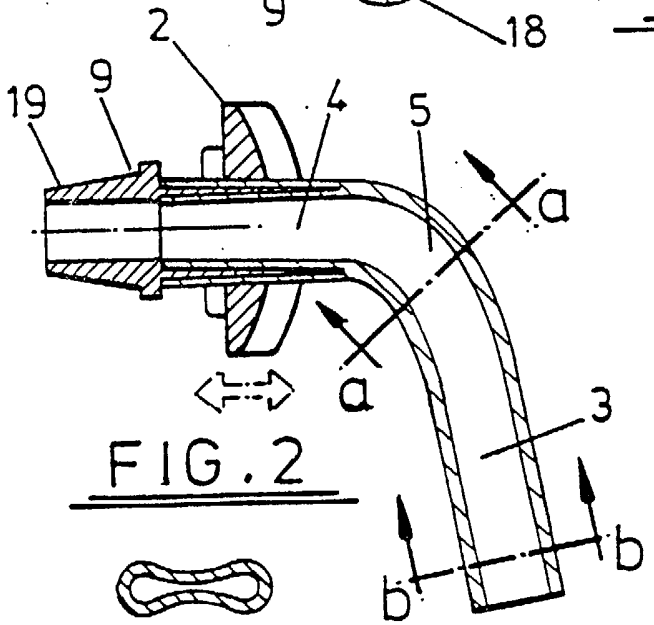

FIG. 2

FIG. 2c

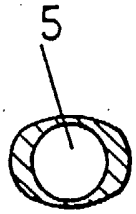

FIG. 2a

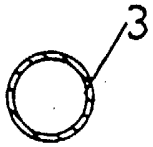

FIG. 2b

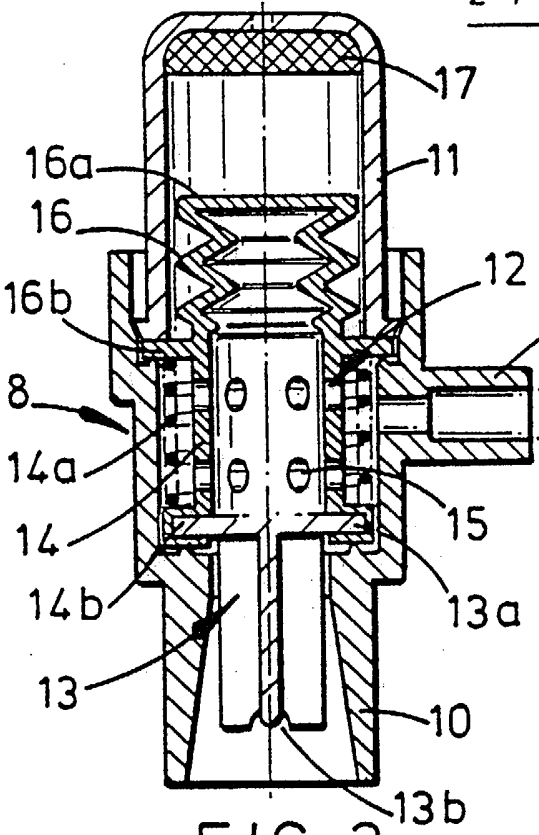

FIG. 3

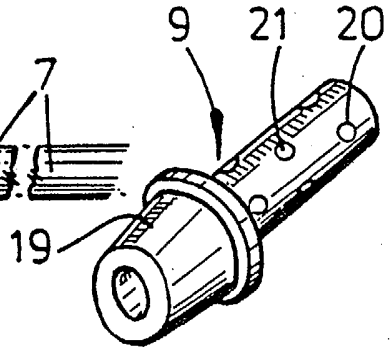

FIG. 4

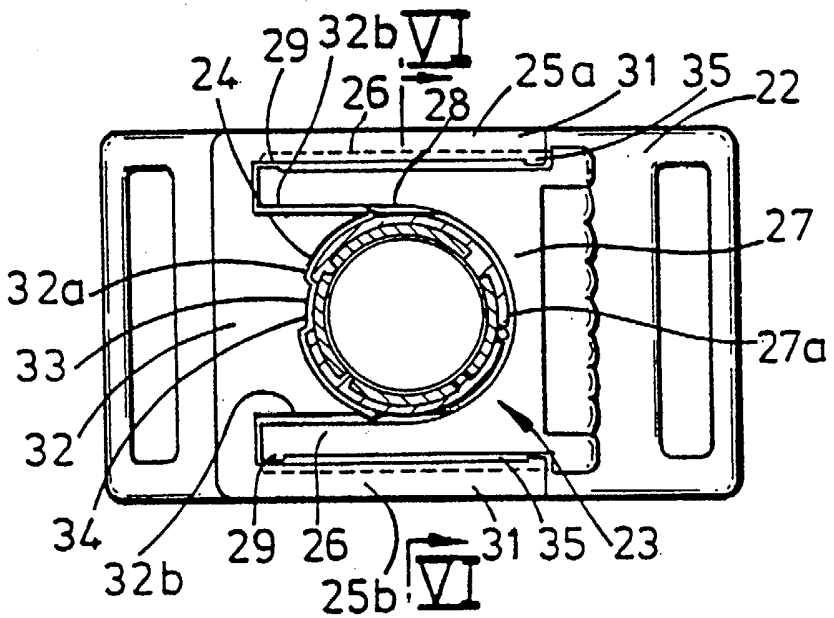

FIG. 5

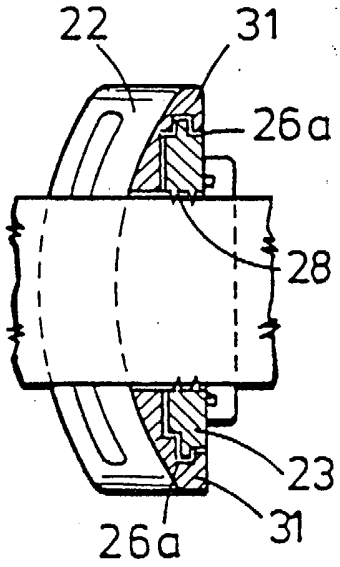

FIG. 6

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 93/01097

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl.5 A 61 M 16/04 A 61 M 25/00

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl.5	A 61 M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	FR,A,2293222 (FINSEN LOMHOLT) 2 July 1976 see page 1, line 1 - line 34 see page 3, line 21 - line 28 see page 4, line 1 - line 20 see page 4, line 32 - line 34 see figures 2,3 ---	1,3,4
X	WO,A,9204071 (BILLINO) 19 March 1992 see page 7, line 20 - line 26 see figure 2 ---	1,3
X	US,A,4305392 (CHESTER) 15 December 1981 see column 1, line 48 - column 2, line 15 see figures 1,2 --- -/-	1

° Special categories of cited documents :[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
30-08-1993	16. 11. 93
International Searching Authority	Signature of Authorized Officer
EUROPEAN PATENT OFFICE	J.F.E SCHÖNLEBEN

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
X	FR,A,2655548 (VAN CLEEF) 14 June 1991 see page 1, line 25 - page 2, line 8 see figures 1,2	1,3
A	US,A,4050466 (KOERBACHER) 27 September 1977 see column 2, line 52 - line 63 see column 3, line 3 - line 8 see figure 1	4

INTERNATIONAL SEARCH REPORT

International application No.
PCT/GB93/01097

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

For further information seeForm PCT/ISA/206 sent on 15.09.93.

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. ☐ As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-4

Remark on Protest

☐ The additional search fees were accompanied by the applicant's protest.

☐ No protest accompanied the payment of additional search fees.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9301097 SA 75509

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 08/11/93
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
FR-A- 2293222	02-07-76	CH-A- 596842	31-03-78
		DE-A,C 2553307	24-06-76
		GB-A- 1526286	27-09-78
		JP-A- 51092590	13-08-76
		NL-A- 7513957	04-06-76
		SE-B- 423315	03-05-82
		SE-A- 7513525	03-06-76
WO-A- 9204071	19-03-92	DE-U- 9012370	06-12-90
		EP-A- 0545928	16-06-93
US-A- 4305392	15-12-81	None	
FR-A- 2655548	14-06-91	None	
US-A- 4050466	27-09-77	None	